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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ALTER, ALYSSA MARGO	
ART UNIT	**PAPER NUMBER**
3762	

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05/08/2012	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/799,534	YU ET AL.	
	Examiner	Art Unit	
	Alyssa M. Alter	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2012*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1,3-6,8-10,12 and 14-27* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,3-6,8-10,12,14-18 and 21-27* is/are rejected.

8)☒ Claim(s) *19 and 20* is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *12 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed January 11, 2012 have been fully considered but they are not persuasive. The Applicant argues the inlet connector 10 and the curved section 76 disclosed in Poirier do not form an inflow tube and adapter sleeve forming an extended inflow tube configured to pass through a wall of a ventricular apex of a heart (as now recited in the now amended claim 1).

2. However, the claims remain rejected Poirier (US 4,086,665) and Jassawalla et al. in an alternative interpretation (see below).

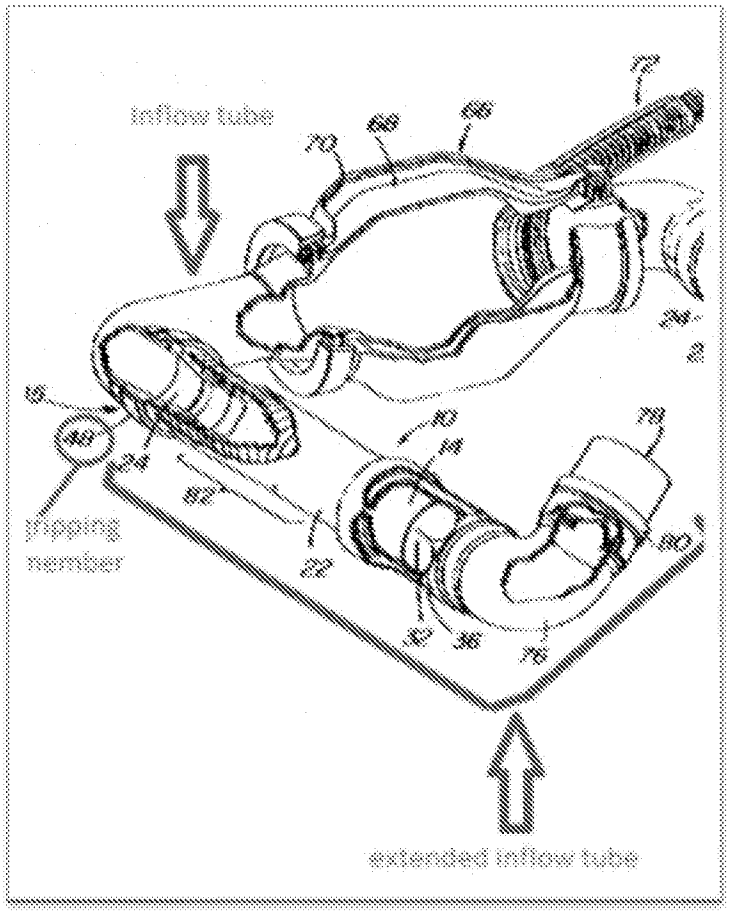
Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3, 8-10, 18 and 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Poirier (US 4,086,665). Poirier discloses a pump (depicted in figure 3 as 66), an inflow tube protruding from the pump portion (depicted in the replica of figure 3 below), an adapter sleeve (curved section 76 and inlet tube 78 in figure 3) extending from the inflow tube and forming an extended inflow tube with a greater length and a gripping member (coupling 48 in figure 3) having an opening and being configured to

receive the extended inflow tube (see figure 3 and the replica of figure 3 below).



5. As to claim 3, Poirier discloses a sewing ring (depicted as 80 in figure 3). The sewing ring anchors the extended inflow tube to the apex of the heart. Therefore, the sewing ring attaches the gripping member, which is located on the extended inflow tube, to the apex of the heart.

6. As to claim 8, the inflow tube (inlet connect 10) included a bend end (adjacent to coupling 48). A replica of the bent portion of the inflow tube for figure 3 is included at right.

7. As to claims 9-10, the inflow tube (inlet connector 10) engages with the threaded end connector 36 of the adapter sleeve (curved section 76). The connection between the inflow tube and the threaded adapter can be seen in figure 1. In order to connect the inflow tube with the adapter sleeve, the inflow tube is necessarily rotatable in order to engage the threads of the inflow tube (retainer 38 and tube 14) with the threads of the end connector. Furthermore, the examiner considers the retainer 38 of the inflow tube to be the “extendable end” that extends to engage with the end connector 36.

8. As to claim 18, as described above, Poirier discloses a cylindrical sleeve (curved section 76 and inlet tube 78 in figure 3) that is fitted over the inflow tube of the ventricle assist pump inflow tube (see the replica of figure 3 above). Furthermore, since the examiner considers the cylindrical sleeve to be the entire portion of the extended inflow tube (see figure 3 above), the extended inflow tube engages with the apex of the heart (col. 4, lines 29-36). In addition, Poirier discloses a coupling (sewing ring depicted as 80 in figure 3) which is configured to attach the cylindrical sleeve to the apex of the heart.

9. As to claim 21, as stated above, Poirier discloses a sewing ring (depicted as 80 in figure 3) as a coupling to engage the cylindrical sleeve to the apex of the heart.

10. As to claim 22, as stated above, Poirier discloses a sewing ring (depicted as 80 in figure 3) as a coupling to engage the cylindrical sleeve to the apex of the heart. The examiner further considers the inlet tube 78, to include the suture ring 80, to be the ventricular apex connector. The sewing ring inherently has a surface, and since a surface inherently has a texture, the surface of the sewing ring necessarily has a textured surface. Additionally, sewing rings are typically comprised of a fabric or porous

material to affix with sutures to tissue. Therefore, the sewing ring necessarily includes a textured surface.

11. As to claim 23, as depicted in the cut-away portion of figure 3, the ventricular apex connector (inlet tube 78) has an inside diameter configured for sealing engaging with an outside diameter surface of the cylindrical sleeve (curved section 76, which is part of the extended inflow tube).

12. As to claim 24, as stated above, the ventricular apex connector (inlet tube 78) is composed of a cylindrical ring having at least two apertures (as depicted in figure 3).

13. Claims 18 and 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Jassawalla et al. (US 6,001,056). Jassawalla et al. discloses a ventricular assist device with a pump (pumping portion 14 depicted in figures 1 and 2), an inflow tube (valved segment 22 in figures 1 and 2), adapter sleeve (flexible segment 26, depicted in figures 1-2, as well as figures 4-5). The examiner additionally considers the inflow tube, the adapter sleeve and tubular cannula body (depicted 186 in figure 5). together form the extended inflow tube. The extended inflow tube is configured to pass through the apex of the heart (see figure 1). The examiner considers the sewing ring, located on the tubular cannula body to be the coupling portion configured to attach the cylindrical sleeve to the apex of the heart.

14. As to claim 21, as stated above, the examiner considers the sewing ring, located on the tubular cannula body to be the coupling portion configured to attach the cylindrical sleeve to the apex of the heart.

15. As to claim 22, Jassawalla et al. discloses the sewing ring includes a fabric covering (col. 6, lines 46-52). Therefore, the fabric necessarily provides a textured surface. Additionally, as stated above, the sewing ring is located on the tubular cannula body, which the examiner considers to be a "ventricular apex connector".

16. As to claims 23-24, the “ventricular apex connector” (tubular cannula body) engages with the external surface of the extended inflow tube (see figure 5) and includes at least two apertures (additionally seen in figure 5).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 4, 6, 15-16 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poirier (US 4,086,665). Poirier discloses the employment of biologically compatible titanium (col. 2, lines 38-39) but does not explicitly disclose the adapter sleeve is a smooth cylinder of titanium. Poirier discloses the device substantially as claimed except for the adapter sleeve being titanium or ceramic

material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the material used for the adapter sleeve, since such a modification of the material would provide the predictable results of providing sufficient structure while maintaining in-vivo biocompatibility. Furthermore, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin, 125 USPQ 416* (See MPEP 2144.07)

20. As to claim 12, as depicted above in the replica of figure 3, Poirier discloses a pump, an inflow tube protruding from the pump portion, an adapter sleeve attached to the inflow tube to from an extended inflow tube that engages with the apex of the heart, as well as a sewing ring (depicted as 80 in figure 3). Additionally, Poirier includes a coupling (inlet tube 78). As to the "gripping" portion, the examiner considers the threads of the inlet tube 78 (see the cutaway of figure 3) to be the "gripping" portion of the "gripping member" that couples to the exterior surface of the extended inflow tube. Accordingly, the modified Poirier as applied to claims 4 and 6 above, discloses a biocompatible tube made of titanium. Furthermore, the examiner considers the threads to function as gripping pads to attach the coupling.

21. Alternatively, although the examiner considers the modified Poirier to disclose gripping pads, the modified Poirier does not explicitly disclose "gripping pads".

22. As to claims 12, 15-16 and 25-26, Poirier discloses the device substantially as claimed but does not disclose the inclusion of gripping pins or rods and gripping pads. It would have been obvious to one having ordinary skill in the art at the time the invention

was made to include gripping pins or rods with gripping pads to ensure that the connection between the two components be maintained even in the event that the threaded connection becomes "stripped" (i.e. the threaded connection no longer creates a reliable connection) during attachment.

23. Claims 1, 3-6, 8-10, 12, 14-17 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jassawalla et al. (US 6,001,056) in view of Poirier (US 4,086,665). Jassawalla et al. discloses a ventricular assist device with a pump (pumping portion 14 depicted in figures 1 and 2), an inflow tube (valved segment 22 in figures 1 and 2), adapter sleeve (flexible segment 26, depicted in figures 1-2, as well as figures 4-5). The inflow tube and the adapter sleeve together form the extended inflow tube. The adapter sleeve has a coupler fitting (coupling 182 in figure 4) for mating with the inflow tube (col. 5, lines 25-38). Additionally, the examiner considers the extended inflow tube to include the tubular cannula body (depicted 186 in figure 5), which is configured to pass through the apex of the heart (see figure 1).

24. Jasswalla et al. additionally discloses stitch(es) 196 and 194 to couple the sewing ring to the exterior surface of the extended inflow tube (see fig.5). Jasswalla et al. discloses the device substantially as claimed with gripping members (stitches) but does not explicitly disclose a gripping member having an opening configured to receive the extended inflow tube. Poirier discloses a threaded coupling as a gripping member between the extended inflow tube, inlet 10, and the inlet tube 76 that includes the suture ring 80. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the connection between the inflow tube and the sewing

ring (stiches) of Jasswalla et al. for the threaded connection between the inflow tube and the suture ring of Poirier in order to provide the predictable results of enabling a reliable and secure coupling that will be properly aligned and less dependent on the skill of the surgeon (i.e. in making appropriately placed and secure stitches).

25. As to claim 3, the ventricle assist device includes a sewing ring (depicted as 166 in figures 4-5). As depicted in figure 1, the tubular cannula body (186 in figure 5) is inserted into the ventricular apex of the heart. Therefore, the modified Jasswalla et al. discloses a sewing ring for engaging the gripping member to the apex of the heart.

26. As to claim 5, Jassawalla et al. discloses a reinforcement cage (112 and 164 in figures 3 and 5 respectively) with the adapter sleeve. As such, the examiner considers the adapter sleeve to include the reinforcement cage. The reinforcement cage includes ribs 116 bridges 118 and axial spaces 120. Therefore, the axial spaces, or grooves, form perforations on the adapter sleeve that “separate the adapter sleeve”.

27. As to claims 4 and 6, the modified Jassawalla et al. discloses the device substantially as claimed except for the adapter sleeve being titanium or ceramic material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the material used for the adapter sleeve, since such a modification of the material would provide the predictable results of providing sufficient structure while maintaining in-vivo biocompatibility. Furthermore, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin, 125 USPQ 416* (See MPEP 2144.07)

28. As to claim 8, the modified Jassawalla et al. discloses the claimed invention except for the inflow tube including the bent end. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the inflow tube to include the bent end instead of the pump, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse, 86 USPQ 70* (see MPEP 2144.04). Furthermore, such a modification would not alter the circulation of the blood but merely relocates the bent end from the pump to the end of the inflow tube that engages with the pump.

29. As to claim 9, the examiner considers the inflow tube of Jasswalla et al. to have an “extendable end” since one of the ends is configured to be attached to the adapter and thus extended. Thus, since the adapter is added to the inflow tube, the inflow tube includes an extendable end.

30. As to claim 10, the modified Jassawalla et al. teaches a threaded attachment between the extended inflow tube and the sewing ring (as seen in Porier figure 1). In order to connect the threaded extended inflow tube with the threaded component possessing the suture ring, the inflow tube is necessarily rotatable in order to engage the threads of the inflow tube with the threads of the suturing ring component.

31. Alternatively, the modified Jassawalla et al. discloses the claimed invention except for the inflow tube including a rotatable end. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the inflow tube to include the rotatable end instead of the adapter sleeve, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse,*

86 USPQ 70 (see MPEP 2144.04). Furthermore, such a modification would not substantially alter the engagement of the inflow tube and the adapter but merely changes which component has the coupler fitting.

32. As to claim 12, Jassawalla et al. discloses the reinforcement cage, which is attached to the adapter sleeve, permits the adapter sleeve to extend and contract (col. 6, lines 4-14). Therefore, the examiner considers the reinforcement cage to be the "adjustable attachment member configured to attach to the adapter sleeve" (as stated above in reference to claim 14).Therefore, the modified Jassawalla et al., as applied to claim 4 above, discloses an adapter sleeve (segment 26) made of titanium with an attached adjustable attachment member (reinforcement cage 122).

33. As to claim 14, Jassawalla et al. discloses a reinforcement cage (112 and 164 in figures 3 and 5 respectively). "The reinforcement cage 112 includes a plurality of circumferentially formed ribs 116 joined at periodic locations by bridges 118. Although not shown well in FIG. 3, the bridges 118 are circumferentially offset from each other from rib-to-rib to enable the reinforcement cage 112 to be axially extended (this is better seen in the conduit segment of the present invention seen in perspective in FIG. 4). That is, the cage 112 is desirably formed of a resilient biocompatible material such as polypropylene, and axial elongation of the segment 100 is permitted by virtue of the ribs 116 bending to enlarge the axial spaces 120 therebetween"(col. 6, lines 4-14). Thus the reinforcement cage, which is attached to the adapter sleeve, permits the adapter sleeve to extend and contract. Therefore, the examiner considers the reinforcement cage to be the "adjustable attachment member configured to attach to the adapter sleeve".

34. As to claims 15-17 and 25-27, the modified Jassawalla et al. discloses the device substantially as claimed except for the gripping members being gripping pins for engaging with cylindrical ring and spring ring. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the gripping members of Jassawalla et al. to include gripping pins that engagement with cylindrical and spring rings in order to provide the predictable results of ensuring the adapter sleeve and reinforcement cage are sufficiently attached to the sewing ring of the ventricle assist device. Furthermore, such a modification to include pins enables proper positioning of the reinforcement cage on the ventricle assist device.

Claim Objections

35. Claims 19-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

36. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Niketa I. Patel/
Supervisory Patent Examiner, Art Unit 3762

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